ROCHE FREEDMAN LLP
Ivy T. Ngo (249860)
Velvel (Devin) Freedman (*pro hac vice forthcoming*)
Constantine P. Economides (*pro hac vice forthcoming*)
200 South Biscayne Boulevard
Miami, Florida 33131
Telephone: (305) 971-5943
Facsimile: (646) 392-8842
Emails: ingo@rcfllp.com
vel@rcfllp.com
ceconomides@rcfllp.com

Counsel for Plaintiff

[Additional Counsel on Signature Page]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

THOMAS LEONARD, Individually and on Behalf of All Others Similarly Situated,

Plaintiff,

vs.

FIBROGEN, INC., ENRIQUE CONTERNO, JAMES SCHOENECK, and K. PEONY YU,

Defendants.

Case No.:

CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

JURY TRIAL DEMANDED

Plaintiff Thomas Leonard ("Plaintiff"), individually and on behalf of all others similarly situated hereby bring this complaint against FibroGen, Inc. ("FibroGen" or the "Company"), Enrique Conterno ("Conterno"), James Schoeneck ("Schoeneck"), and K. Peony Yu ("Yu") (collectively, "Defendants"). The allegations herein are based on Plaintiff's personal knowledge as to his own acts and on information and belief as to all other matters, such information and belief having been informed by the investigation conducted by and under the supervision of counsel, which includes a review of: U.S. Securities and Exchange Commission ("SEC") filings by FibroGen; securities analysts' reports and advisories about the Company; press releases and other public statements issued by the Company; media reports about the Company; and information obtainable on the Internet. Counsel's investigation into the matters alleged herein is ongoing and many relevant facts are known only to Defendants, or are exclusively within their custody or control. Plaintiff's investigation indicates substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. NATURE OF THE ACTION

1. This is a federal securities class action on behalf of all persons and entities who purchased or otherwise acquired FibroGen securities and/or sold put options during the period from October 18, 2017 to April 6, 2021, inclusive (the "Class Period"), and were damaged thereby ("the Class"). The action is brought against FibroGen and certain of its officers for violations of the Securities Exchange Act of 1934 (the "Exchange Act") and SEC Rule 10b-5 promulgated thereunder.

2. FibroGen is a commercial-stage biopharmaceutical company whose lead product candidate is roxadustat (Roxa), a drug aimed at treating anemia in individuals with chronic kidney disease ("CKD"). The kidneys in CKD individuals cannot properly filter blood or make the hormone erythropoietin, which tells the body to make more oxygen-carrying red blood cells.

3. One out of seven Americans, or 17% of the population, faces CKD. Of those individuals, 23% suffer from anemia – the loss of red blood cells which can increase the chance of a heart attack because less oxygen is supplied to the heart muscle. Anemia increases with the

severity of CKD. As a result, most CKD anemia individuals undergo dialysis three times a week, during which they receive infusions of iron or an erythropoietin-stimulating agent ("ESA") such as Epogen (epoetin alfa). Other CKD anemia individuals remain undertreated due in part to concerns over ESA safety. This market for ESAs is expected to exceed $17 billion by 2025.

4. The Class Period begins on October 18, 2017 when FibroGen announced that the China Food and Drug Administration ("CFDA") had accepted its new drug application ("NDA") for Roxa based on two Phase 3 studies in China, "one study in CKD dialysis comparing roxadustat against a branded epoetin alfa[] and one study in CKD non-dialysis comparing roxadustat against placebo."[1] Both studies had "met their primary efficacy endpoints with ***no new or unexpected safety signals identified***." The Company touted these studies' positive safety results for the rest of the Class Period.

5. Having overcome the hurdle of demonstrating to the CFDA that Roxa was safe enough to submit an NDA, FibroGen proceeded to present itself as ready to conduct Phase 3 trials sufficient to support an NDA to the U.S. Food and Drug Administration ("FDA"). And as those Phase 3 trials progressed, Defendants raised no concerns or issues with the safety data that was being obtained, and indeed, stated August 7, 2018 that they were "***on track*** with timelines for regulatory submission of roxadustat for the treatment of CKD anemia in multiple regions," including the U.S.

6. Thus, FibroGen appeared poised to enter the ESA market as the first FDA-approved, orally available drug to compete with infused drugs like Epogen when it announced positive topline results from three global Phase 3 trials on December 20, 2018. Specifically, "[t]he preliminary safety analyses of each of these three individual studies show an ***overall safety profile consistent with the results observed in prior roxadustat studies***. The ***adverse events reported are consistent with those expected*** in these study populations with similar background diseases."

7. But for the FDA to approve Roxa, Defendants knew that "one of the key safety endpoints to be evaluated [wa]s Major Adverse Cardiac Events (MACE), a composite endpoint of

[1] Unless otherwise noted, internal citations are omitted and emphasis is added.

all-cause mortality, stroke and myocardial infarction, in pooled analyses against placebo in NDD [non-dialysis dependent patients] and against epoetin alfa in DD [dialysis-dependent patients] from the pivotal Phase 3 trials."

8. As a result, when the safety data did not meet the requisite statistical threshold to claim that Roxa was not inferior to Epogen (as Defendants knew or recklessly disregarded would happen), Defendants simply claimed that there was "***no clinically meaningful difference***" in announcing the "***Positive Topline Results from Pooled Safety Analyses*** of Roxadustat Global Phase 3 Program" after the markets closed on May 9, 2019. But there was no getting around the fact that that "[i]n the pooled analyses of around 4,000 dialysis patients, ***the upper bound of the 95% confidence interval (CI) was below the pre-specified non-inferiority margin*** for the time to first MACE+ analyses" and that "[i]n the non-dialysis pool of approximately 4,300 patients, non-inferiority was demonstrated for roxadustat compared to placebo in the time to first MACE+, based on ***the upper bound of the 95% CI being below the prespecified non-inferiority margin***."

9. On these revelations, the Company's share price fell $10.53, or 23%

10. As an analyst with The Motley Fool noted in a May 10, 2019 article, shares of FibroGen "***dropped more than 26%*** today after the company reported top-line results from a phase 3 clinical trial" in a press release which "stated that the largest of three patient populations ***didn't meet the statistical threshold specified in the study to claim that the drug candidate is noninferior to Epogen***, but the company said it believed there was 'no clinically meaningful difference in risk.'" The article further pointed out that "[w]hen asked about this ***subtle but important difference*** on the conference call, CEO Thomas Neff stated that the U.S. Food and Drug Administration had not agreed on the statistical threshold for noninferiority in the first place. That left analysts thinking ***regulators could question the drug candidate's safety profile***, especially since it likely has to be as safe as erythropoiesis-stimulating agents such as Epogen to be approved."

11. Despite the data in front of them, Defendants' refrain in Company press releases, during investor calls, and at scientific conferences for the rest of the Class Period that Roxa appeared to be as safe as, if not safer than, epoetin alfa based on the global Phase 3 studies.

12. For example, on November 8, 2019, FibroGen issued a press release announcing full pooled Phase 3 safety analyses "***demonstrat[ing] a cardiovascular safety profile*** comparable with placebo in patients not on dialysis, and ***comparable or in some cases better than that of epoetin alfa*** in patients on dialysis." Specifically, in the NDD population, "[r]isks of MACE, MACE+, and all-cause mortality in roxadustat patients were ***comparable to placebo*** in the ITT [intent-to-treat] analyses based on a reference non-inferiority margin of 1.3." In the DD population, "[r]isks of MACE and all-cause mortality in roxadustat patients were ***not increased*** compared to those for patients receiving epoetin alfa based on a reference non-inferiority margin of 1.3" and "[r]isk of MACE+ was ***14% lower*** in roxadustat-treated patients than in those receiving epoetin alfa." And in the ID subgroup of the DD population, "[r]isk of MACE was ***30% lower*** in roxadustat patients than in epoetin alfa patients, and risk of MACE+ was ***34% lower***" and "[r]oxadustat-treated patients' risk showed a trend towards ***lower*** all-cause mortality relative to epoetin alfa-treated patients."

13. But, as Defendants knew or should have known, the safety data from the global Phase 3 studies had been manipulated to make Roxa look safer than it is. Investors only found out after the markets closed on April 6, 2021, when FibroGen issued a press release "provid[ing] ***clarification of certain prior disclosures of U.S. primary cardiovascular safety analyses*** from the roxadustat Phase 3 program for the treatment of anemia of chronic kidney disease:"

> "As members of senior management were preparing for the upcoming FDA Advisory Committee meeting, we became aware that ***the primary cardiovascular safety analyses included post-hoc changes to the stratification factors***," said Enrique Conterno, Chief Executive Officer, FibroGen.
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> * * *
>
> The table below describes the cardiovascular safety results using the post-hoc stratification factors reported at the American Society of Nephrology conference in November 2019, as well as the analyses with the pre-specified stratification factors which have not been previously publicly reported.

	Analyses with post-hoc stratification factors	Analyses with pre-specified stratification factors
	HR (95% Confidence Interval)	HR (95% Confidence Interval)
Non Dialysis (OLYMPUS, ANDES, ALPS N=4,270); ITT		
MACE	1.08 (0.94, 1.24)	1.10 (0.96, 1.27)
MACE+	1.04 (0.91, 1.18)	1.07 (0.94, 1.21)
ACM	1.06 (0.91, 1.23)	1.08 (0.93, 1.26)
Dialysis Dependent (HIMALAYAS, SIERRAS, ROCKIES N=3,880); OT-7		
MACE	0.96 (0.82, 1.13)	1.02 (0.88, 1.20)
MACE+	0.86 (0.74, 0.98)	0.91 (0.80, 1.05)
ACM	0.96 (0.79, 1.17)	1.02 (0.84, 1.23)
Incident Dialysis (N=1,526); OT-7		
MACE	0.70 (0.51, 0.96)	0.82 (0.60, 1.11)
MACE+	0.66 (0.50, 0.89)	0.78 (0.59, 1.02)
ACM	0.76 (0.52, 1.11)	0.82 (0.57, 1.18)

ITT: intention to treat with long-term follow up
OT-7: on-treatment plus 7 days
Major Adverse Cardiovascular Event (MACE): a composite endpoint of all-cause mortality, stroke, and myocardial infarction.
(MACE+): in addition to the components in MACE, includes hospitalization due to heart failure or unstable angina.
(ACM): all-cause mortality.

As reflected in the table, the analyses with the pre-specified stratification factors result in higher hazard ratios (point estimates of relative risk) and 95% confidence intervals. For MACE+ in dialysis and for MACE and MACE+ in incident dialysis, the 95% confidence intervals include 1.0. While these hazard ratios remain below 1.0, ***based on these analyses we cannot conclude that roxadustat reduces the risk of (or is superior to) MACE+ in dialysis, and MACE and MACE+ in incident dialysis compared to epoetin-alfa.***

14. On this news, the Company's share price fell $15.83, or 46%.

15. As explained in an article published by STAT+ on April 6, 2021 titled "Fibrogen admits false heart-safety data for experimental anemia pill shared with FDA, investors:"

> [Defendants] acknowledged Tuesday that the company has been touting ***false heart-safety data for its experimental anemia pill for at least two years — a shocking revelation that raises even more questions about the drug's approvability***. Shares of Fibrogen fell 27% to $25 in Tuesday's after-hours trading session as investors questioned the credibility of the company's management team and mulled the ramifications of revised heart-safety data that may no longer be strong enough to pass muster with the Food and Drug Administration…Fibrogen was expecting the FDA to complete its review of roxadustat and render an approval decision by March 20. But in a surprising — and concerning — move announced just three weeks before that deadline, the FDA instead decided to convene a meeting of outside experts to review the drug's clinical data. The FDA advisory panel meeting is tentatively scheduled for July 15.
>
> ***
>
> But Tuesday, Fibrogen said that while preparing for the FDA advisory panel, it discovered the ***post-hoc changes to the heart safety "stratification factors."*** When those changes were removed and roxadustat's heart-safety specified in the analysis plan, the results are less robust.

Across three studies involving dialysis patients, ***Fibrogen said it can no longer conclude that roxadustat reduces the risk of cardiovascular events or hospitalization compared to a currently approved anemia injection used as a control.***

16. Analysts covering FibroGen were stunned by this revelation:

- Raymond James: "[T]he dataset is messy and indicates that overall risk/benefit profile of roxa is questionable, at best."
- Mizuho: "[W]e were surprised by this update and find it difficult to understand if this was a one-off unintentional mistake, or more."
- HC Wainwright: "[T]his unfavorable disclosure changes our view on roxa approvability and potential market uptake."

17. In sum, Defendants made repeated misrepresentations and omissions that artificially inflated the price of FibroGen's securities. Specifically, during the Class Period, Defendants made false and/or misleading statements or failed to disclose that: (i) based on the safety data from FibroGen's two Phase 3 trials in China, any safety data obtained from the global Phase 3 trials would require post-hoc changes to the stratification factors to meet the FDA's requirements; (ii) FibroGen's disclosures of U.S. primary cardiovascular safety analyses from the Roxa global Phase 3 program for the treatment of anemia certain safety analyses submitted in connection with CKD included post-hoc changes to the stratification factors; (iii) FibroGen's analyses with the pre-specified stratification factors resulted in higher hazard ratios (point estimates of relative risk) and 95% confidence intervals; (iv) based on these analyses, FibroGen could not conclude that Roxa reduces the risk of (or is superior to) MACE+ in dialysis, and MACE and MACE+ in incident dialysis compared to epoetin-alfa; (v) as a result, FibroGen faced significant uncertainty that its NDA for Roxa as a treatment for anemia of CKD would be approved by the FDA; and (vi) as a result of the foregoing, Defendants' statements about the Company's business, operations, and prospects were materially false and misleading and/or lacked a reasonable basis at all relevant times.

18. Defendants' false and/or misleading statements caused FibroGen securities to trade at inflated prices during the Class Period. After disclosure of Defendants' false and misleading statements and/or materialization of their concealed risks, FibroGen securities suffered a precipitous decline in market value, thereby causing significant losses and damages to Plaintiff and the Class.

II. JURISDICTION AND VENUE

19. The claims asserted herein arise under §§ 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

20. This Court has jurisdiction over the subject matter of this Action pursuant to 28 U.S.C. § 1331 and § 27 of the Exchange Act (15 U.S.C. § 78aa).

21. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and § 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Many of the acts charged herein, including the dissemination of materially false and/or misleading information, occurred in substantial part in this Judicial District. In addition, FibroGen is headquartered in this Judicial District.

22. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the U.S. Mail, interstate telephone communications, and the facilities of a national securities exchange.

III. PARTIES

23. Plaintiff Leonard acquired FibroGen securities, as set forth in the accompanying certification which is incorporated by reference herein, at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged disclosures and/or materialization of Defendants' concealed risk.

24. Defendant FibroGen is a Delaware corporation and maintains its principal executive offices in San Francisco, California. The Company's common stock is listed on the NASDAQ under the ticker symbol "FGEN."

25. Defendant Conterno has served as the Company's Chief Executive Officer ("CEO") since January 3, 2020.

26. Defendant Schoeneck served as interim CEO from August 2019 to January 3, 2020.

27. Defendant Yu served as Chief Medical Officer from April 2016 until December 20, 2020.

28. Defendants Conterno, Schoeneck and Yu are collectively referred to herein as the "Individual Defendants."

29. Because of the Individual Defendants' executive positions, they each had access to the undisclosed adverse information about FibroGen's business, operations, operational trends, controls, markets, and present and future business prospects *via* internal corporate documents, conversations and connections with other corporate officers and employees, attendance at management and Board meetings and committees thereof, including the Executive Committee.

30. It is appropriate to treat Defendants as a group for pleading purposes and to presume that the false, misleading and incomplete information conveyed in the Company's public filings, press releases and other publications, as alleged herein, are the collective actions of the narrowly defined group of Defendants identified above. Each of the Individual Defendants was directly involved in the management and day-to-day operations of the Company at the highest levels and was privy to confidential proprietary information concerning the Company and its business, operations, controls, growth, products and present and future business prospects as alleged herein. In addition, the Individual Defendants were involved in drafting, producing, reviewing and/or disseminating the false and/or misleading statements and information alleged herein, were aware of, or recklessly disregarded, the false and misleading statements being issued regarding the Company, and approved or ratified these statements in violation of the federal securities laws.

31. As officers and controlling persons of a publicly-held company whose shares are registered with the SEC pursuant to the Exchange Act and trade on the NASDAQ which is governed by the federal securities laws, each Individual Defendant had a duty to promptly disseminate accurate and truthful information with respect to FibroGen's operations, business, products, markets, management, and present and future business prospects. In addition, each Individual Defendant had a duty to correct any previously-issued statements that had become materially misleading or untrue, so that the market price of FibroGen's publicly-traded shares would be based upon truthful and accurate information. Defendants' false and/or misleading misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

32. The Individual Defendants, because of their positions of control and authority as Officers and Directors of the Company, were able to, and did, control the content of the various SEC filings, press releases and other public statements pertaining to the Company during the Class Period. Each Individual Defendant was provided with copies of the documents alleged herein to be misleading before or shortly after their issuance or had the ability or opportunity to prevent their issuance or cause them to be corrected. Accordingly, each Individual Defendant is responsible for the accuracy of the public statements detailed herein and is, therefore, primarily liable for the representations contained therein.

33. Each Defendant is liable as a participant in a fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of FibroGen shares by disseminating materially false and/or misleading statements and/or concealing material adverse facts.

IV. SUBSTANTIVE ALLEGATIONS

34. FibroGen is a biopharmaceutical company that develops medicines for the treatment of anemia, fibrotic disease, and cancer. Its most advanced product is Roxa, an oral small molecule inhibitor of hypoxia-inducible factor prolyl hydroxylase ("HIF-PH") activity that acts by stimulating the body's natural pathway for red cell production. In 2019, the Company filed its NDA with the FDA for the approval of Roxa for the treatment of anemia due to chronic kidney disease ("CKD").

35. Anemia can be a serious medical condition in which patients have insufficient red blood cells and low levels of hemoglobin, a protein in red blood cells that carries oxygen to cells throughout the body. Anemia in CKD is associated with increased risk of hospitalization, cardiovascular complications and death, also frequently causing significant fatigue, cognitive dysfunction, and reduced quality of life. Severe anemia is common in patients with CKD, cancer, myelodysplastic syndromes ("MDS"), inflammatory diseases, and other serious illnesses.

36. Anemia is particularly prevalent in patients with CKD. The prevalence of CKD in the adult population is estimated at 10-12% globally and is generally a progressive disease characterized by gradual loss of kidney function that may eventually lead to kidney failure, or end stage renal

disease, requiring dialysis or kidney transplant to survive. Blood transfusion is used for treating life-threatening severe anemia. However, blood transfusions reduce the patient's opportunity for kidney transplant, and increase the risk of infections and the risk of complications such as heart failure and allergic reactions.

37. According to the United States Renal Data System ("USRDS"), over 14% of the U.S. adult population is affected by CKD, and a majority of dialysis-eligible CKD patients are currently on dialysis. It is estimated that approximately 509,000 patients are receiving dialysis in the U.S. as of 2016.

38. Roxa (FG-4592) purports to be an orally administered small molecule HIFPH inhibitor that promotes erythropoiesis through increasing endogenous production of erythropoietin, improving iron regulation, and overcoming the negative impact of inflammation on hemoglobin syntheses and red blood cell production by downregulating hepcidin. The Company states that administration of Roxa has been shown to induce coordinated erythropoiesis, increasing red blood cell count while maintaining plasma erythropoietin levels within or near normal physiologic range in multiple subpopulations of CKD patients, including in the presence of inflammation and without a need for supplemental intravenous iron.

V. MATERIALLY FALSE AND MISLEADING STATEMENTS

39. The Class Period begins on October 18, 2017 when FibroGen announced *via* a press release the acceptance of its NDA for Roxa by the China Food and Drug Administration ("CFDA").[2] The Company stated that this NDA was based on its two Phase 3 "studies conducted in China, one study in CKD dialysis comparing roxadustat against a branded epoetin alfa[] and one study in CKD non-dialysis comparing roxadustat against placebo," both of which "met their primary efficacy endpoints with ***no new or unexpected safety signals identified***."

[2] *FibroGen Announces Acceptance by China FDA of Roxadustat New Drug Application (NDA) for Treatment of Anemia Associated With Dialysis and Non-Dialysis Chronic Kidney Disease (CKD)*, GLOBENEWSWIRE (Oct. 18, 2017, 07:00 ET), https://www.globenewswire.com/news-release/2017/10/18/1149112/0/en/FibroGen-Announces-Acceptance-by-China-FDA-of-Roxadustat-New-Drug-Application-NDA-for-Treatment-of-Anemia-Associated-With-Dialysis-and-Non-Dialysis-Chronic-Kidney-Disease-CKD.html.

40. On February 27, 2018, FibroGen reported *via* a press release financial results for the fourth quarter ("4Q17") and full year 2017 ("FY2017").[3] In the press release, FibroGen reiterated the "***[p]ositive*** efficacy and ***safety results*** reported from two Phase 3 trials" for Roxa in China.

41. On June 7, 2018, FibroGen announced *via* a press release completion of patient enrollment in the U.S. Phase 3 clinical program for Roxa.[4] In the press release, the Company declared that topline results and the pooled safety analyses from those studies "will ***support the submission of an NDA*** in the first half of 2019" to the FDA.

42. On August 7, 2018, FibroGen reported *via* a press release financial results for the second quarter 2018 ("2Q18").[5] In the press release, Neff stated that "we are ***on track*** with timelines for regulatory submission of roxadustat for the treatment of CKD anemia in multiple regions, as we have made significant progress toward approval in China, and our ***studies for U.S. approval are completing*** and will read out in the fourth quarter of this year."

43. On October 25, 2018, FibroGen presented *via* a press release results from the two Phase 3 studies in China.[6] In the press release, the Company stated that in both studies, Roxa

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[3] *FibroGen Reports Fourth Quarter and Full Year 2017 Financial Results*, GLOBENEWSWIRE (Feb. 27, 2018, 16:11 ET), https://www.globenewswire.com/en/news-release/2018/02/27/1396459/33525/en/FibroGen-Reports-Fourth-Quarter-and-Full-Year-2017-Financial-Results.html.

[4] *FibroGen Announces Completion of Enrollment in U.S. Phase 3 Clinical Program for Roxadustat in Anemia Associated with Chronic Kidney Disease*, GLOBENEWSWIRE (June 07, 2018, 07:00 ET), https://www.globenewswire.com/en/news-release/2018/06/07/1518273/33525/en/FibroGen-Announces-Completion-of-Enrollment-in-U-S-Phase-3-Clinical-Program-for-Roxadustat-in-Anemia-Associated-with-Chronic-Kidney-Disease.html.

[5] *FibroGen Reports Second Quarter 2018 Financial Results*, GLOBENEWSWIRE (Aug. 07, 2018, 16:02 ET), https://www.globenewswire.com/en/news-release/2018/08/07/1548417/33525/en/FibroGen-Reports-Second-Quarter-2018-Financial-Results.html.

[6] *FibroGen Presents Results from Two Phase 3 Studies of Roxadustat for the Treatment of Anemia Associated with Chronic Kidney Disease Conducted in China at American Society of Nephrology Kidney Week 2018 Annual Meeting*, GLOBENEWSWIRE (Oct. 25, 2018, 19:49 ET), https://www.globenewswire.com/news-release/2018/10/25/1627610/33525/en/FibroGen-Presents-Results-from-Two-Phase-3-Studies-of-Roxadustat-for-the-Treatment-of-Anemia-Associated-with-Chronic-Kidney-Disease-Conducted-in-China-at-American-Society-of-Nephro.html.

"appeared to be well-tolerated [], ***there were no safety signals, and the most frequent treatment emergent adverse events were typical*** for this population." FibroGen further noted that:

> Globally, the Phase 3 program encompasses a total of 15 Phase 3 studies of roxadustat in both non-dialysis-dependent and dialysis-dependent CKD patients to support independent regulatory approvals in the U.S., Europe, Japan, and China. To date, ***positive topline results have been announced for seven of the Phase 3 studies***, with two supporting the China NDA for treatment of anemia in CKD patients on dialysis and not on dialysis, four supporting the Japan NDA for treatment of anemia in CKD patients on dialysis, and ***one supporting the U.S./EU submissions***.

44. On November 8, 2018, FibroGen reported *via* a press release financial results for the third quarter 2018 ("3Q18").[7] In the press release, Neff stated that "[w]ith new drug applications for roxadustat in anemia associated with chronic kidney disease supported by ***positive Phase 3 results*** and under review in China and Japan, we look forward to the upcoming ***reporting of topline clinical results, pooled safety data and submitting our U.S. NDA.***"

45. On December 20, 2018, FibroGen announced *via* a press release positive topline results from three global Phase 3 trials of Roxa ("December 20 Press Release").[8] Two of the studies specifically assessed Roxa compared to epoetin alfa, one with CKD patients who had newly initiated dialysis treatment (HIMALAYAS) and one with CKD patients who were receiving stable does of ESA (SIERRA). In the press release, FibroGen stated that "[t]he preliminary ***safety analyses of each of these three individual studies show an overall safety profile consistent with the results observed in prior roxadustat studies***. ***The adverse events reported are consistent with those expected*** in these study populations with similar background diseases."

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[7] *FibroGen Reports Third Quarter 2018 Financial Results*, GLOBENEWSWIRE (Nov. 08, 2018, 16:02 ET), https://www.globenewswire.com/en/news-release/2018/11/08/1648491/33525/en/FibroGen-Reports-Third-Quarter-2018-Financial-Results.html.

[8] *FibroGen Announces Positive Topline Results from Three Global Phase 3 Trials of Roxadustat for Treatment of Anemia in Patients with Chronic Kidney Disease*, GLOBENEWSWIRE (Dec. 20, 2018, 07:00 ET), https://www.globenewswire.com/en/news-release/2018/12/20/1670189/33525/en/FibroGen-Announces-Positive-Topline-Results-from-Three-Global-Phase-3-Trials-of-Roxadustat-for-Treatment-of-Anemia-in-Patients-with-Chronic-Kidney-Disease.html.

46. On February 27, 2019, FibroGen reported *via* a press release financial results for the fourth quarter ("4Q18") and full year 2017 ("FY2018").[9] The press release quoted Neff as stating that "[f]ollowing the release of positive efficacy data from our Phase 3 program, ***our team is now preparing for the submission of our U.S. NDA to the FDA in 2019***."

47. On May 9, 2019, FibroGen announced *via* a press release titled "FibroGen Announces ***Positive Topline Results from Pooled Safety Analyses*** of Roxadustat Global Phase 3 Program" ("Pooled Safety Press Release") that "MACE/MACE+ endpoints evaluated across CKD patients not on dialysis and on dialysis ***Superiority in time to first MACE+ versus epoetin alfa*** in incident [newly initiated] dialysis patients."[10]

48. In the Pooled Safety Press Release, FibroGen specifically detailed the safety analyses and conclusions from its Phase 3 trials in three populations:

> **Pooled MACE/MACE+ in DD-CKD Population**
>
> In the pooled analyses of around 4,000 dialysis patients, the upper bound of the 95% confidence interval (CI) was below the pre-specified non-inferiority margin for the time to first MACE+ analyses. Based on the MACE safety analyses of this population, we believe ***there is no clinically meaningful difference in risk of MACE between roxadustat and epoetin alfa***.
>
> **Pooled MACE/MACE+ in Incident Dialysis CKD Subpopulation**
>
> The roxadustat global Phase 3 program enrolled over 1,500 incident dialysis patients, a subpopulation of DD-CKD population, which we believe offers a better setting for comparing roxadustat to epoetin alfa than the stable dialysis population, that is stable on both dialysis and erythropoiesis stimulating agent (ESA). Roxadustat demonstrated superiority to epoetin alfa in the time to first MACE+ in this subpopulation. In the MACE analysis, ***there is a trend toward reduced risk for patients on roxadustat, compared to epoetin alfa***.
>
> **Pooled MACE/MACE+ in NDD-CKD Population**

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[9] *FibroGen Reports Fourth Quarter and Full Year 2018 Financial Results*, GLOBENEWSWIRE (Feb. 27, 2019, 16:08 ET), https://www.globenewswire.com/news-release/2019/02/27/1743774/0/en/FibroGen-Reports-Fourth-Quarter-and-Full-Year-2018-Financial-Results.html.

[10] *FibroGen Announces Positive Topline Results from Pooled Safety Analyses of Roxadustat Global Phase 3 Program*, GLOBENEWSWIRE (May 09, 2019, 16:43 ET), https://www.globenewswire.com/news-release/2019/05/09/1821450/33525/en/FibroGen-Announces-Positive-Topline-Results-from-Pooled-Safety-Analyses-of-Roxadustat-Global-Phase-3-Program.html.

> In the non-dialysis pool of approximately 4,300 patients, ***non-inferiority was demonstrated for roxadustat compared to placebo in the time to first MACE+,*** based on the upper bound of the 95% CI being below the prespecified non-inferiority margin. Based on the MACE safety analyses of this population, we believe ***there is no clinically meaningful difference in risk of MACE between roxadustat and placebo***.

49. Further, the Pooled Safety Press Release quoted Neff as stating that "[w]e are very pleased with what we believe are important ***positive results of MACE and MACE+ analyses in the dialysis-dependent, incident dialysis, and non-dialysis dependent CKD patients, supporting the safety of roxadustat in CKD patients***[.]"

50. In addition, the Pooled Safety Press Release quoted Yu as stating that "[w]e are particularly excited about the ***results indicating a reduction of risk of MACE+ events in incident dialysis patients***[.]"

51. Also on May 9, 2019, FibroGen reported *via* a press release financial results for the first quarter 2019 ("1Q19 Press Release") and quoted Neff as stating that "[w]ith respect to the global Roxadustat anemia platform, we received ***positive topline results from analyses of pooled MACE and MACE+ data from our Phase 3 trials evaluating Roxadustat*** as a treatment for dialysis and non-dialysis CKD patients."[11]

52. In the 1Q19 Press Release, FibroGen also reiterated the safety analyses and conclusions from its Phase 3 trials in three populations:

- In the pooled analyses of around 4,000 dialysis patients, the upper bound of the 95% confidence interval (CI) was below the pre-specified non-inferiority margin for the time to first MACE+ analyses. Based on the MACE safety analyses of this population, we believe ***there is no clinically meaningful difference in risk of MACE between roxadustat and epoetin alfa***.
- In the pooled analyses of about 1,500 incident dialysis patients roxadustat demonstrated superiority to epoetin alfa in the time to first MACE+ in this subpopulation. In the MACE analysis, ***there is a trend toward reduced risk for patients on roxadustat, compared to epoetin alfa***.
- In the non-dialysis pool of approximately 4,300 patients, ***non-inferiority was demonstrated for roxadustat compared to placebo in the time to first MACE+***,

[11] *FibroGen Reports First Quarter 2019 Financial Results*, GLOBENEWSWIRE (May 9, 2019, 16:44 ET), https://www.globenewswire.com/news-release/2019/05/09/1821452/33525/en/FibroGen-Reports-First-Quarter-2019-Financial-Results.html.

based on the upper bound of the 95% CI being below the pre-specified non-inferiority margin.

53. On October 11, 2019, FibroGen announced *via* a press release that "[p]ooled efficacy and cardiovascular safety of roxadustat, compared to epoetin alfa (EPO) in CKD patients on dialysis and compared to placebo in CKD patients not on dialysis, to be presented as late-breaker" at the American Society of Nephrology Kidney Week 2019.[12] Specifically, "***[c]onfirmed global Phase 3 pooled efficacy and cardiovascular safety results*** [were] to be presented at late-breaker session on Friday, November 8, at 2pm."

54. On November 7, 2019, FibroGen announced *via* a press release "Phase 3 Efficacy and Safety Results for Roxadustat Versus Epoetin Alfa as Treatment of Anemia in Incident Dialysis Patients with Chronic Kidney Disease".[13] In the press release, the Company specifically stated that "[t]he ***safety profile of roxadustat observed in the HIMALAYAS trial was consistent with results observed in previous roxadustat studies***" and the "***[d]ata from the HIMALAYAS trial is included in pooled efficacy and cardiovascular safety analyses of the roxadustat Phase 3 clinical development program***, which will be presented during the ASN Kidney Week High-Impact Clinical Trials oral abstract session."

55. The next day, on November 8, 2019, the Company issued a press release titled "Positive Phase 3 Pooled Roxadustat Safety and Efficacy Results" (11/8/19 Press Release).[14] The

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[12] *Roxadustat Global Phase 3 Results for Treatment of Chronic Kidney Disease (CKD) Anemia to be Presented at American Society of Nephrology Kidney Week 2019*, GLOBENEWSWIRE (Oct. 11, 2019, 10:58 ET), https://www.globenewswire.com/news-release/2019/10/11/1928703/33525/en/Roxadustat-Global-Phase-3-Results-for-Treatment-of-Chronic-Kidney-Disease-CKD-Anemia-to-be-Presented-at-American-Society-of-Nephrology-Kidney-Week-2019.html.

[13] *FibroGen Presents Phase 3 Efficacy and Safety Results for Roxadustat Versus Epoetin Alfa as Treatment of Anemia in Incident Dialysis Patients with Chronic Kidney Disease*, GLOBENEWSWIRE (Nov. 07, 2019, 16:39 ET), https://www.globenewswire.com/news-release/2019/11/07/1943618/33525/en/FibroGen-Presents-Phase-3-Efficacy-and-Safety-Results-for-Roxadustat-Versus-Epoetin-Alfa-as-Treatment-of-Anemia-in-Incident-Dialysis-Patients-with-Chronic-Kidney-Disease.html.

[14] *FibroGen Announces Positive Phase 3 Pooled Roxadustat Safety and Efficacy Results for Treatment of Anemia in Chronic Kidney Disease*, GLOBENEWSWIRE (Nov. 08, 2019, 14:10 ET), https://www.globenewswire.com/news-release/2019/11/08/1944228/33525/en/FibroGen-

press release quoted Robert Provenzano, MD, Associate Professor of Medicine, Wayne State University, and a primary investigator on the global Phase 3 program, as stating that:

> The ***pooled safety analyses assessing roxadustat as a treatment for anemia in chronic kidney disease demonstrate a cardiovascular safety profile*** comparable with placebo in patients not on dialysis, and ***comparable or in some cases better than that of epoetin alfa in patients on dialysis***. . . . ***These positive safety results***, coupled with roxadustat's well-defined efficacy in CKD patients, and its oral formulation, ***support the potential for roxadustat to become an important new treatment option*** for patients with anemia associated with CKD.

56. In the 11/8/19 Press Release, FibroGen explained that in the global Phase 3 studies:

Cardiovascular (CV) endpoints were defined as:

- Time to first Major Adverse Cardiovascular Event (MACE): a composite endpoint of all-cause mortality, myocardial infarction, stroke;
- Time to first MACE+, a composite endpoint which includes MACE plus unstable angina and heart failure requiring hospitalization; and
- Time to all-cause mortality

-- In the Non-Dialysis Dependent (NDD) patient population:
- Risks of MACE, MACE+, and all-cause mortality in roxadustat patients were comparable to placebo in the ITT analyses based on a reference non-inferiority margin of 1.3.

-- In a post hoc subgroup analysis of 2,438 non-dialysis patients with baseline eGFR≥15,
- The one-year decline in eGFR in roxadustat treated patients (-2.8) was significantly less than that in placebo treated patients (-4.4), with a treatment difference of 1.6 mL/min/1.73m2 ($p<0.0001$).

-- In the Dialysis Dependent (DD) patient population:
- Risks of MACE and all-cause mortality in roxadustat patients were not increased compared to those for patients receiving epoetin alfa based on a reference non-inferiority margin of 1.3.
- Risk of MACE+ was 14% lower in roxadustat-treated patients than in those receiving epoetin alfa.

-- The Incident Dialysis (ID) patient sub-group of the Dialysis Dependent (DD) patient population:
- Risk of MACE was 30% lower in roxadustat patients than in epoetin alfa patients, and risk of MACE+ was 34% lower.
- Roxadustat-treated patients' risk showed a trend towards lower all-cause mortality relative to epoetin alfa-treated patients.

57. The 11/8/19 Press Release also quoted Yu as stating that:

Announces-Positive-Phase-3-Pooled-Roxadustat-Safety-and-Efficacy-Results-for-Treatment-of-Anemia-in-Chronic-Kidney-Disease.html.

> "***The positive efficacy and cardiovascular safety results from these pooled analyses***, in a population with a broad range in both CKD and anemia severity in over 8,000 patients across six Phase 3 global trials, ***reaffirm the potential of roxadustat to improve treatment for anemia in CKD patients***."

58. A couple days later, on November 11, 2019, FibroGen reported *via* a press release financial results for the third quarter 2019 ("3Q19 Press Release").[15] The press release quoted Schoeneck as stating that "[w]e expect ***the positive cardiovascular safety data, comparing roxadustat to placebo in non-dialysis patients and to epoetin alfa in patients on dialysis, along with the superior efficacy results, can serve as the basis for regulatory approval in the U.S.*** and other jurisdictions."

59. In the 3Q19 Press Release, FibroGen also summarized the clinical results from the global Roxa Phase 3 studies:

- ***Cardiovascular Safety Confirmed*:** In both non-dialysis dependent and dialysis dependent CKD anemia patients:
  - **Non-Dialysis Dependent (NDD)** (n=4270):
    - ***Risk of MACE, MACE+, and all-cause mortality in roxadustat patients was comparable to placebo based on a reference non-inferiority margin of 1.3***
    - NDD results are based on ITT long-term follow-up analysis method agreed with the FDA
  - **Dialysis Dependent (DD)** (n=3880):
    - ***Risk of MACE and all-cause mortality in roxadustat patients were not increased compared to the active comparator, epoetin alfa***
    - ***Roxadustat patients had a 14% lower risk of MACE+ than epoetin alfa patients***
  - **Incident Dialysis (ID) Subgroup** (n=1526): In the clinically important ID subgroup of patients, initiating dialysis within 4 months prior to randomization:
    - ***Roxadustat patients had a 30% lower risk of MACE than epoetin alfa***
    - ***Roxadustat patients had a 34% lower risk of MACE+ than epoetin alfa***
    - ***Roxadustat patients had a trend towards lower all-cause mortality compared to epoetin alfa***

[15] *FibroGen Reports Third Quarter 2019 Financial Results*, GLOBENEWSWIRE (Nov. 11, 2019, 16:01 ET), https://www.globenewswire.com/news-release/2019/11/11/1944925/33525/en/FibroGen-Reports-Third-Quarter-2019-Financial-Results.html.

60. On December 23, 2019, FibroGen announced *via* a press release that it had submitted its NDA for Roxa to the FDA ("12/23/19 Press Release").[16] In the press release, the Company noted that "***[r]egulatory approval of roxadustat is supported by positive results from a global Phas*** On February 11, 2020, FibroGen announced *via* a press release that the FDA had completed its filing review of its NDA for Roxa and ***e 3 program*** encompassing 15 trials that enrolled more than 10,000 patients, worldwide."

61. The 12/23/19 Press Release also quoted Schoeneck as stating that "[t]he ***submission of this NDA is a major step toward our goal of bringing this novel oral medicine to U.S. patients*** suffering from anemia in CKD."

62. On February 11, 2020, FibroGen announced *via* a press release that the FDA had completed its filing review of its NDSA for Roxa and set a December 20, 2020 Prescription Drug User Fee Act ("PDUFA") date ("2/11/20 Press Release").[17] The press release quoted Conterno as stating that "***[t]he FDA's acceptance of the roxadustat new drug application is a critical step towards providing a new treatment option in the United States*** for chronic kidney disease patients suffering from anemia, a serious and often life-threatening disease."

63. On May 7, 2020, FibroGen issued a press release reporting financial results for the first quarter 2020 ("1Q20 Press Release").[18] The press release noted that the Company had

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[16] *FibroGen Submits New Drug Application to the U.S. FDA for Roxadustat in Patients With Anemia of Chronic Kidney Disease*, GLOBENEWSWIRE (Dec. 23, 2019, 07:00 ET), https://www.globenewswire.com/en/news-release/2019/12/23/1963997/33525/en/FibroGen-Submits-New-Drug-Application-to-the-U-S-FDA-for-Roxadustat-in-Patients-With-Anemia-of-Chronic-Kidney-Disease.html.

[17] *FibroGen Announces U.S. FDA Acceptance of New Drug Application for Roxadustat for the Treatment of Anemia of Chronic Kidney Disease*, GLOBENEWSWIRE (Feb. 11, 2020, 17:00 ET), https://www.globenewswire.com/en/news-release/2020/02/11/1983461/33525/en/FibroGen-Announces-U-S-FDA-Acceptance-of-New-Drug-Application-for-Roxadustat-for-the-Treatment-of-Anemia-of-Chronic-Kidney-Disease.html.

[18] *FibroGen Reports First Quarter 2020 Financial Results*, GLOBENEWSWIRE (May 07, 2020, 16:01 ET), https://www.globenewswire.com/news-release/2020/05/07/2029835/33525/en/FibroGen-Reports-First-Quarter-2020-Financial-Results.html.

"[p]resented new analyses from our Phase 3 roxadustat trials at the annual National Kidney Foundation Spring Clinical meeting which demonstrated:

- Roxadustat corrected and maintained hemoglobin in non-dialysis dependent patients with anemia using similar doses regardless of iron status at baseline.
- ***Roxadustat reduced the risk of red blood cell transfusions and IV iron rescue compared to placebo in non-dialysis CKD patients, regardless of iron status at baseline***.
- ***Roxadustat reduced the risk of red blood cell transfusion during anemia treatment in dialysis dependent CKD patients vs. epoetin alfa***.

64. On October 14, 2020, the Company issued a press release titled "Fibrogen to Present New Efficacy and Safety Analyses from Roxadustat Global Phase 3 Program at American Society of Nephrology Kidney Week 2020 Reimagined" (10/14/20 Press Release).[19] The press release quoted Conterno as stating that "[o]ur ***roxadustat clinical data at*** **ASN Kidney Week 2020 Reimagined** ***demonstrate consistent efficacy and positive safety results*** across the continuum of chronic kidney disease patients with anemia, adding to the established body of evidence highlighting roxadustat as a potential foundational treatment for this condition affecting millions of patients."

65. On December 2, 2020, the Company issued a press release titled "FibroGen to Present Safety and Efficacy Analyses from Roxadustat Global Phase 3 Program at American Society of Hematology Annual Meeting" (12/2/20 Press Release).[20] The press release quoted Conterno as stating that "we are presenting ***Phase 3 cardiovascular safety and efficacy results of roxadustat***, which ***highlight its potential in a broad range of CKD patients***."

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[19] *FibroGen to Present New Efficacy and Safety Analyses from Roxadustat Global Phase 3 Program at American Society of Nephrology Kidney Week 2020 Reimagined*, GLOBENEWSWIRE (Oct. 14, 2020, 07:00 ET), https://www.globenewswire.com/news-release/2020/10/14/2108241/33525/en/FibroGen-to-Present-New-Efficacy-and-Safety-Analyses-from-Roxadustat-Global-Phase-3-Program-at-American-Society-of-Nephrology-Kidney-Week-2020-Reimagined.html.

[20] *FibroGen to Present Safety and Efficacy Analyses from Roxadustat Global Phase 3 Program at American Society of Hematology Annual Meeting*, GLOBENEWSWIRE (Dec. 02, 2020, 07:00 ET), https://www.globenewswire.com/news-release/2020/12/02/2138189/33525/en/FibroGen-to-Present-Safety-and-Efficacy-Analyses-from-Roxadustat-Global-Phase-3-Program-at-American-Society-of-Hematology-Annual-Meeting.html.

66. On December 18, 2020, FibroGen announced *via* a press release that the FDA had extended the review period of the Roxa NDA by three months and updated the PDUFA action date to March 20, 2021.[21] In the press release, the Company stated that "[t]he FDA is close to finalizing its review of the NDA and ***FibroGen is submitting additional analyses of existing roxadustat clinical data***, which require an extension of the original PDUFA date."

67. The above statements identified in ¶¶ 35-66 were materially false and/or misleading because Defendants misrepresented and/or failed to disclose the following adverse facts about FibroGen's business, operations, and prospects, which were known to Defendants or recklessly disregarded by them that: (i) based on the safety data from FibroGen's two Phase 3 trials in China, any safety data obtained from the global Phase 3 trials would require post-hoc changes to the stratification factors to meet the FDA's requirements; (ii) FibroGen's disclosures of U.S. primary cardiovascular safety analyses from the Roxa global Phase 3 program for the treatment of anemia certain safety analyses submitted in connection with CKD included post-hoc changes to the stratification factors; (iii) FibroGen's analyses with the pre-specified stratification factors resulted in higher hazard ratios (point estimates of relative risk) and 95% confidence intervals; (iv) based on these analyses, FibroGen could not conclude that Roxa reduces the risk of (or is superior to) MACE+ in dialysis, and MACE and MACE+ in incident dialysis compared to epoetin-alfa; (v) as a result, FibroGen faced significant uncertainty that its NDA for Roxa as a treatment for anemia of CKD would be approved by the FDA; and (vi) as a result of the foregoing, Defendants' statements about the Company's business, operations, and prospects were materially false and misleading and/or lacked a reasonable basis at all relevant times.

VI. THE TRUTH IS REVEALED

68. Despite putting as positive spin as possible on the safety analyses (*see supra* ¶¶ 47-52), Defendants were forced to reveal to investors on May 9, 2019 that the study data did not meet the requisite statistical threshold to claim that Roxa was not inferior to Epogen. The press releases

[21] *FibroGen Provides Regulatory Update on Roxadustat*, GLOBENEWSWIRE (Dec. 18, 2020, 16:59 ET), https://www.globenewswire.com/en/news-release/2020/12/18/2148127/33525/en/FibroGen-Provides-Regulatory-Update-on-Roxadustat.html.

specifically stated that "[i]n the pooled analyses of around 4,000 dialysis patients, ***the upper bound of the 95% confidence interval (CI) was below the pre-specified non-inferiority margin*** for the time to first MACE+ analyses" and that "[i]n the non-dialysis pool of approximately 4,300 patients, non-inferiority was demonstrated for roxadustat compared to placebo in the time to first MACE+, based on ***the upper bound of the 95% CI being below the prespecified non-inferiority margin***."

69. On these revelations, the Company's share price fell $10.53, or 23%, to close at $35.14 per share on May 13, 2019, on usually heavy volume.

70. On May 10, 2019, The Motley Fool published an article by Maxx Chatsko titled "Here's Why Fibrogen Fell as Much as 26.6% Today: The company reported confusing top-line results from an important batch of phase 3 safety studies. Were they successful?"[22] The article explained that:

> ***Shares of FibroGen (NASDAQ:FGEN) dropped more than 26% today after the company reported top-line results from a phase 3 clinical trial***. . . . Seemingly contradictory phrases in the press release and statements on the first-quarter 2019 earnings conference call left room for Wall Street to cast the top-line results in a negative light. Reporting from FierceBiotech takes the "glass half full" perspective, noting that Jefferies analysts think the company's choice of certain words and phrases made the data appear worse than they are. But not everyone on Wall Street is so sure.
>
> As of 1:58 p.m. EDT, the stock had settled to a 22.5% loss.
>
> * * *
>
> ***The press release stated that the largest of three patient populations didn't meet the statistical threshold specified in the study to claim that the drug candidate is noninferior to Epogen, but the company said it believed there was "no clinically meaningful difference in risk."***
>
> When asked about this subtle but important difference on the conference call, CEO Thomas Neff stated that ***the U.S. Food and Drug Administration had not agreed on the statistical threshold for noninferiority in the first place. That left analysts thinking regulators could question the drug candidate's safety profile, especially since it likely has to be as safe as erythropoiesis-stimulating agents such as Epogen to be approved***.

[22] Maxx Chatsko, *Here's Why FibroGen Fell as Much as 26.6% Today*, THE MOTLEY FOOL (May 10, 2019, 02:29 PM), https://www.fool.com/investing/2019/05/10/heres-why-fibrogen-fell-as-much-as-266-today.aspx.

71. After the markets closed on April 6, 2021, FibroGen issued a press release "provid[ing] ***clarification of certain prior disclosures of U.S. primary cardiovascular safety analyses*** from the roxadustat Phase 3 program for the treatment of anemia of chronic kidney disease ("CKD"):"

> "As members of senior management were preparing for the upcoming FDA Advisory Committee meeting, we became aware that ***the primary cardiovascular safety analyses included post-hoc changes to the stratification factors***," said Enrique Conterno, Chief Executive Officer, FibroGen.
>
> * * *
>
> The table below describes the cardiovascular safety results using the post-hoc stratification factors reported at the American Society of Nephrology conference in November 2019, as well as the analyses with the pre-specified stratification factors which have not been previously publicly reported.

	Analyses with post-hoc stratification factors	Analyses with pre-specified stratification factors
	HR (95% Confidence Interval)	HR (95% Confidence Interval)
Non Dialysis (OLYMPUS, ANDES, ALPS N=4,270); ITT		
MACE	1.08 (0.94, 1.24)	1.10 (0.96, 1.27)
MACE+	1.04 (0.91, 1.18)	1.07 (0.94, 1.21)
ACM	1.06 (0.91, 1.23)	1.08 (0.93, 1.26)
Dialysis Dependent (HIMALAYAS, SIERRAS, ROCKIES N=3,880); OT-7		
MACE	0.96 (0.82, 1.13)	1.02 (0.88, 1.20)
MACE+	0.86 (0.74, 0.98)	0.91 (0.80, 1.05)
ACM	0.96 (0.79, 1.17)	1.02 (0.84, 1.23)
Incident Dialysis (N=1,526); OT-7		
MACE	0.70 (0.51, 0.96)	0.82 (0.60, 1.11)
MACE+	0.66 (0.50, 0.89)	0.78 (0.59, 1.02)
ACM	0.76 (0.52, 1.11)	0.82 (0.57, 1.18)

ITT: intention to treat with long-term follow up
OT-7: on-treatment plus 7 days
Major Adverse Cardiovascular Event (MACE): a composite endpoint of all-cause mortality, stroke, and myocardial infarction.
(MACE+): in addition to the components in MACE, includes hospitalization due to heart failure or unstable angina.
(ACM): all-cause mortality.

> As reflected in the table, the analyses with the pre-specified stratification factors result in higher hazard ratios (point estimates of relative risk) and 95% confidence intervals. For MACE+ in dialysis and for MACE and MACE+ in incident dialysis, the 95% confidence intervals include 1.0. While these hazard ratios remain below 1.0, ***based on these analyses we cannot conclude that roxadustat reduces the risk of (or is superior to) MACE+ in dialysis, and MACE and MACE+ in incident dialysis compared to epoetin-alfa.***

72. On this news, the Company's share price fell $15.83, or 46%, to close at $18.81 per share on April 8, 2021, on usually heavy volume.

73. As explained in an article published by STAT+ on April 6, 2021 titled "Fibrogen admits false heart-safety data for experimental anemia pill shared with FDA, investors," Defendants

> [A]cknowledged Tuesday that the company has been touting ***false heart-safety data for its experimental anemia pill for at least two years — a shocking revelation that raises even more questions about the drug's approvability***. Shares of Fibrogen fell 27% to $25 in Tuesday's after-hours trading session as investors questioned the credibility of the company's management team and mulled the ramifications of revised heart-safety data that may no longer be strong enough to pass muster with the Food and Drug Administration…Fibrogen was expecting the FDA to complete its review of roxadustat and render an approval decision by March 20. But in a surprising — and concerning — move announced just three weeks before that deadline, the FDA instead decided to convene a meeting of outside experts to review the drug's clinical data. The FDA advisory panel meeting is tentatively scheduled for July 15.
>
> ***
>
> But Tuesday, Fibrogen said that while preparing for the FDA advisory panel, it discovered the ***post-hoc changes to the heart safety "stratification factors."*** When those changes were removed and roxadustat's heart-safety specified in the analysis plan, the results are less robust.
>
> Across three studies involving dialysis patients, ***Fibrogen said it can no longer conclude that roxadustat reduces the risk of cardiovascular events or hospitalization compared to a currently approved anemia injection used as a control***.[23]

74. Analysts covering FibroGen were stunned by this revelation:

- A Raymond James analyst said "the dataset is messy and indicates that overall risk/benefit profile of roxa is questionable, at best."
- A Mizuho analyst cut FibroGen to Neutral from a Buy and slashed the price target to $29 from $72, commenting "we were surprised by this update and find it difficult to understand if this was a one-off unintentional mistake, or more."
- An HC Wainwright analyst downgraded the stock to Neutral from Buy stating, "this unfavorable disclosure changes our view on roxa approvability and potential market uptake."

VII. ADDITIONAL SCIENTER ALLEGATIONS

75. The Individual Defendants knew and/or recklessly disregarded the falsity and misleading nature of the information that they caused to be disseminated to the investing public. The ongoing fraudulent scheme described herein could not have been perpetrated over a substantial

[23] Adam Feuerstein, *Fibrogen admits false heart-safety data for experimental anemia pill shared with FDA, investors*, STAT (Apr. 06, 20121), https://www.statnews.com/2021/04/06/fibrogen-admits-false-heart-safety-data-for-experimental-anemia-pill-shared-with-fda-investors/.

period of time without the knowledge and complicity of the personnel at the highest level of the Company, including the Individual Defendants. The Individual Defendants were motivated to materially misrepresent the true nature of the Company's business, operations, and financial affairs to the public and regulators in order to keep the Company's share price artificially high.

76. Defendants were acutely aware that the FDA was focused on how safe Roxa was in assessing whether to approve it. As the Pooled Safety Press Release stated on May 9, 2019:

- For the planned new drug application (NDA) submission to the U.S. Food and Drug Administration (FDA), one of the ***key safety endpoints*** to be evaluated is Major Adverse Cardiac Events (MACE), a composite endpoint of all-cause mortality, stroke and myocardial infarction, in pooled analyses against placebo in NDD and against epoetin alfa in DD from the pivotal Phase 3 trials. Our NDA submission package to the FDA will be based on the totality of evidence, and we will continue to discuss the specific statistical standards with the FDA.

77. Throughout the Class Period, Defendants assured investors that they were in close communication with the FDA regarding the agency's requirements for approval of Roxa:

- 5/9/19 (FibroGen): "Our NDA submission package to the FDA will be based on the totality of evidence, and we will ***continue to discuss the specific statistical standards with the FDA***."
- 5/9/19 (FibroGen): "***ITT is among the several statistical methods that we will discuss with the FDA. In these analyses, roxadustat was comparable based on a commonly applied non-inferiority margin of 1.3***."
- 5/9/19 (FibroGen): "FibroGen and AstraZeneca will ***begin discussions with the U.S. FDA to prepare for regulatory submission***, which is anticipated in September or October of 2019."
- 5/9/19 (Yu): "As we accumulate a body of evidence of roxadustat efficacy and safety with these adjudicated pooled analyses, we look forward to ***begin discussions with U.S. FDA on NDA submission***."
- 12/23/19 (Schoeneck): "We, in collaboration with our partner AstraZeneca, look forward to ***working with the FDA during the NDA review***, and to the potential of roxadustat as a new therapeutic option for treating CKD anemia, in patients on dialysis and not on dialysis."
- 2/11/20 (Yu): "We intend to ***work closely with the FDA***, in collaboration with our partner, AstraZeneca, ***to make this novel oral therapy available as soon as possible***."
- 12/18/20 (Conterno): "FibroGen is ***working closely with the FDA***, in collaboration with our partner, AstraZeneca, ***to support the final review of the new drug application for roxadustat.***"

VIII. LOSS CAUSATION/ECONOMIC LOSS

78. The false and misleading misrepresentations and material omissions, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class members he represents.

79. During the Class Period, Plaintiff and Class members purchased FibroGen securities at artificially inflated prices and were damaged thereby. The price of the Company's securities declined significantly when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were disseminated and publicly revealed.

80. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of FibroGen securities, by publicly issuing false and/or misleading statements and/or omitting to disclose material facts necessary to make Defendants' statements, as set forth herein, not false and/or misleading. The statements and omissions were materially false and/or misleading because they failed to disclose material adverse information and/or misrepresented the truth about FibroGen's business, operations, and prospects, as alleged herein.

81. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiff and other members of the Class. Defendants made or caused to be made materially false and/or misleading statements about FibroGen's business, operations and future prospects. These material misstatements and/or omissions had the cause and effect of creating in the market a false positive assessment of the Company and its business and operational performance and related well-being, thus causing its securities to be overvalued and the price of its securities to be artificially inflated at all relevant times. Defendants' materially false and/or misleading statements, as alleged herein, resulted in Plaintiff and other members of the Class in purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein when the truth was revealed in part on May 9, 2019 and in full on April 6, 2021, causing the trading price of FibroGen securities to materially decline and removing the

previously embedded artificial inflation.

IX. NO SAFE HARBOR

82. The statutory safe harbor under the Private Securities Litigation Reform Act of 1995, which applies to forward-looking statements under certain circumstances, does not apply to any of the allegedly false and misleading statements pleaded in this complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward-looking, they were not adequately identified as "forward-looking statements" when made, and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor is intended to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because, at the time each of those forward-looking statements was made, the particular speaker had actual knowledge that the particular forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized and/or approved by an executive officer of the Company who knew that those statements were false, misleading or omitted necessary information when they were made.

X. CLASS ACTION ALLEGATIONS

83. Plaintiff brings this action as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3) on behalf of a Class, consisting of all persons or entities that purchased or otherwise acquired FibroGen securities during the Class Period and were damaged thereby. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

84. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, FibroGen common stock was actively traded on the NASDAQ. As of October 31, 2020, there were over 91 million shares of FibroGen common stock

outstanding. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by FibroGen or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

85. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

86. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

87. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

a. whether the federal securities laws were violated by Defendants' acts as alleged herein;

b. whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of FibroGen;

c. whether the Individual Defendants caused FibroGen to issue false and misleading financial statements during the Class Period;

d. whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

e. whether the prices of Fibrogen common stock during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

f. whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

88. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of

individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

89. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

a. Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

b. the omissions and misrepresentations were material;

c. FibroGen common stock is traded in an efficient market;

d. the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;

e. the Company traded on the NASDAQ and was covered by multiple analysts;

f. the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

g. Plaintiff and members of the Class purchased, acquired and/or sold FibroGen common stock between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

90. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

91. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

Violations of § 10(b) of the Exchange Act and Rule 10b-5
Against All Defendants

92. Plaintiff repeats and realleges each and every allegation contained in ¶¶ 1-91 as if fully set forth herein.

93. This Count is asserted against Defendants is based upon § 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

94. During the Class Period, Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or

deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

95. Defendants violated § 10(b) of the Exchange Act and Rule 10b-5 in that they:

a. employed devices, schemes and artifices to defraud;

b. made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

c. engaged in acts, practices and a course of business that operated as a fraud or deceit upon Plaintiff and others similarly situated in connection with their purchases of FibroGen common stock during the Class Period.

96. Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of FibroGen were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated, or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the securities laws. These Defendants by virtue of their receipt of information reflecting the true facts of FibroGen, their control over, and/or receipt and/or modification of FibroGen's allegedly materially misleading statements, and/or their associations with the Company which made them privy to confidential proprietary information concerning FibroGen, participated in the fraudulent scheme alleged herein.

97. Individual Defendants, who are the senior officers and/or directors of the Company, had actual knowledge of the material omissions and/or the falsity of the material statements set forth above, and intended to deceive Plaintiff and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth when they failed to ascertain and disclose the true facts in the statements made by them or other FibroGen personnel to members of the investing public, including Plaintiff and the Class.

98. As a result of the foregoing, the market price of FibroGen securities was artificially inflated during the Class Period. In ignorance of the falsity of Defendants' statements, Plaintiff and the other members of the Class relied on the statements described above and/or the integrity of the

market price of FibroGen securities during the Class Period in purchasing FibroGen securities at prices that were artificially inflated as a result of Defendants' false and misleading statements.

99. Had Plaintiff and the other members of the Class been aware that the market price of FibroGen securities had been artificially and falsely inflated by Defendants' misleading statements and by the material adverse information which Defendants did not disclose, they would not have purchased FibroGen common stock at the artificially inflated prices that they did, or at all.

100. As a result of the wrongful conduct alleged herein, Plaintiff and other members of the Class have suffered damages in an amount to be established at trial.

101. By reason of the foregoing, Defendants have violated § 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder and are liable to Plaintiff and the other members of the Class for substantial damages which they suffered in connection with their purchase of FibroGen securities during the Class Period.

COUNT II

Violations of § 20(a) of the Exchange Act
Against the Individual Defendants

102. Plaintiff repeats and realleges each and every allegation contained in ¶¶1-91 as if fully set forth herein.

103. During the Class Period, the Individual Defendants participated in the operation and management of FibroGen, and conducted and participated, directly and indirectly, in the conduct of FibroGen's business affairs. Because of their senior positions, they knew the adverse non-public information about FibroGen's current financial position and future business prospects.

104. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to FibroGen's business practices, and to correct promptly any public statements issued by FibroGen which had become materially false or misleading.

105. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which FibroGen disseminated in the marketplace during the Class Period concerning

the Company's business, operational and accounting policies. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause FibroGen to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of FibroGen within the meaning of § 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of FibroGen common stock.

106. Each of the Individual Defendants, therefore, acted as a controlling person of FibroGen. By reason of their senior management positions and/or being directors of FibroGen, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, FibroGen to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of FibroGen and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

107. By reason of the above conduct, the Individual Defendants are liable pursuant to § 20(a) of the Exchange Act for the violations committed by FibroGen.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Fed. R. Civ. P. 23, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as his reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: May 6, 2021

Respectfully Submitted,

ROCHE FREEDMAN LLP

/s/ Ivy T. Ngo

Ivy T. Ngo (249860)
Velvel (Devin) Freedman (*pro hac vice* forthcoming)
Constantine P. Economides *(pro hac vice* forthcoming)
200 South Biscayne Boulevard
Miami, Florida 33131
Telephone: (305) 971-5943
Emails: ingo@rcfllp.com
vel@rcfllp.com
ceconomides@rcfllp.com

Counsel for Plaintiff and the Class

THE SCHALL LAW FIRM
Brian Schall (290685)
1880 Century Park East, Suite 404
Los Angeles, CA 90067
Telephone: (424) 303-1964
Email: brian@schallfirm.com

Additional Counsel for Plaintiff

CERTIFICATE OF SERVICE

I hereby certify under penalty of perjury that on May 6, 2021, I authorized the electronic filing of the foregoing with the Clerk of the Court using the CM/ECF system which sent notification of such filing to counsel of record.

By: */s/ Ivy T. Ngo*
Ivy T. Ngo

CERTIFICATION PURSUANT TO FEDERAL SECURITIES LAWS

1. I, Thomas J. Leonard, make this declaration pursuant to §27(a)(2) of the Securities Act of 1933 ("Securities Act") and/or §21D(a)(2) of the Securities Exchange Act of 1934 ("Exchange Act") as amended by the Private Securities Litigation Reform Act of 1995.

2. I have reviewed a Complaint against FibroGen, Inc. ("FibroGen" or the "Company") and authorize the filing of a lead plaintiff motion on my behalf.

3. I did not purchase or acquire FibroGen securities at the direction of plaintiffs' counsel or in order to participate in any private action arising under the Securities Act or Exchange Act.

4. I am willing to serve as a representative party on behalf of a Class of investors who purchased or acquired FibroGen securities during the class period, including providing testimony at deposition and trial, if necessary. I understand that the Court has the authority to select the most adequate lead plaintiff in this action.

5. The attached sheet (Schedule "A") lists all of my transactions in FibroGen securities during the Class Period, as specified in the Complaint.

6. During the three-year period preceding the date on which this Certification is signed, I have not served or sought to serve as a representative party on behalf of a class under the federal securities laws.

7. I agree not to accept any payment for serving as a representative party on behalf of the class as set forth in the Complaint, beyond my pro rata share of any recovery, except such reasonable costs and expenses directly relating to the representation of the class as ordered or approved by the Court.

I declare under penalty of perjury that the foregoing is true and correct. Executed this day of 5/1/2021.

DocuSigned by:
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Thomas J. Leonard

SCHEDULE A

Thomas Leonard Transactions in
FibroGen, Inc. ("FGEN")

Date	Transaction	Quantity	Price per Share
04/10/2018	Buy	1,052	$47.249
04/10/2018	Buy	34	$47.50
05/11/2018	Buy	748	$45.40
05/11/2018	Buy	118	$46.40
06/05/2018	Buy	594	$55.4999
06/05/2018	Buy	435	$54.525
06/05/2018	Buy	230	$54.90
06/05/2018	Buy	2,604	$55.136
06/05/2018	Buy	433	$54.9565
07/12/2018	Buy	700	$65.1486
07/12/2018	Buy	487	$65.0999
07/12/2018	Buy	200	$65.0957
10/09/2018	Buy	2	$52.45
10/09/2018	Buy	5,045	$52.75
10/30/2018	Buy	409	$40.598
10/30/2018	Buy	101	$40.55
12/31/2018	Buy	652	$45.98
08/08/2019	Sell	1,844	$46.7901
01/15/2020	Buy	116	$42.75
01/15/2020	Buy	348	$43.0775